PMS8

EQ-5D UTILITY WEIGHTS ASSOCIATED WITH RESPONSE TO TREATMENT WITH MATRIX APPLIED AUTOLOGOUS CULTURED CHONDROCYTES (MACI) IMPLANT AND MICROFRACTURE FOR CARTILAGE DEFECTS OF THE KNEE

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OBJECTIVES: SUMMIT, a 2-year, multicenter, randomised trial, demonstrated significant improvements in pain and function with matrix applied autologous cultured chondrocytes (MACI) implant versus microfracture in patients with symptomatic knee cartilage defects (NCT00719576). We present post-hoc results of the impact of treatment response on EQ-5D utility scores, and the overall incremental impact of treatment with MACI compared with microfracture over 2 years. **METHODS:** Patients (aged 18-55) with Outerbridge Grade III/IV focal cartilage defect ≥3.0cm^{2}were randomised to receive MACI implant (n=72) or microfracture (n=72). Response to treatment was defined as ≥10-point improvement from baseline in both the Knee Injury and Osteoarthritis Outcome (KOOS) pain and function scores at year 2. EQ-5D was evaluated at baseline, and years 1 and 2. Patients' EQ-5D responses were scored using UK-tariffs. Utility values associated with responders and non-responders were estimated based on results from both treatment arms combined. Incremental quality-adjusted life year (QALY) gains were derived by multiplying the difference in response rates between the treatments with the difference in utility between responders and non-responders. **RESULTS:** The mean utility score for all patients (n=142) at baseline was 0.481±0.296. Responders (n=111) had an improvement in mean utility score from baseline of 0.352 (0.833-0.481) compared with 0.033 for non-responders (n=29; 0.514-0.481) at year 2. Significantly more patients treated with MACI responded to treatment than with microfracture (87.5% vs. 68.1%, respectively; p=0.016), resulting in an incremental QALY gain of 0.11 for MACI compared with microfracture over 2 years. **CONCLUSIONS:** At baseline, patients with chondral defects experienced a substantially reduced HRQoL. Significantly more patients responded to treatment with MACI versus microfracture, and this response was associated with substantial improvements in HRQoL. In this population, the higher response rate for MACI resulted in an incremental QALY gain of 0.11 compared with microfracture over 2 years.

PMS9

EARLY RESPONSE TO CERTOLIZUMAB PEGOL IN RHEUMATOID ARTHRITIS PREDICTS OUTCOME AT ONE YEAR

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OBJECTIVES: Treat-to-target strategies for the treatment of rheumatoid arthritis (RA), as recommended in current treatment guidelines, require the use of reliable early markers of treatment response in order to adapt therapy in a timely way in patients with insufficient response. The objective of this study was to evaluate and compare the performance of different clinical indicators in predicting clinical response at one year. **METHODS:** This was a *post-hoc*analysis of data from the RAPID1 randomised, placebo-controlled Phase III study. A total of 382 severe RA patients treated with certolizumab pegol 200mg and no prior TNF inhibitor were assessed by Week 12 (bW12) and at Week 52 (W52). "Insufficient response" was defined using the ACR response criteria, compared to baseline, DAS28 score (Δ<1.2), HAQ score (Δ<0.22) and CDAI (score<22). The ability of insufficient response to these markers bW12 to predict failure to achieve ACR50 at W52, was compared in terms of positive predictive value (PPV), specificity and sensitivity. **RESULTS:** At W52, 149 (38.1%) patients met the ACR50 response criterion. For all bW12 outcome indicators, the specificity and the PPV was >80%. The higher PPVs were observed for bW12 ACR20 non response (1.00 [95%CI: 0.93-1.00]), bW12 reduction in DAS28 (0.95 [95%CI: 0.82-0.99]) and bW12 CDAI score (0.93 [95%CI: 0.85-0.97]). For bW12 ACR20 non response, bW12 reduction in DAS28 and bW12 CDAI score, specificities were respectively 1.00 (95%CI: 0.97-1.00), 0.99 (95%CI: 0.94-1.00) and 0.95 (95%CI: 0.90-0.98). The highest sensitivity was observed for the bW12 ACR50 (0.70 [95%CI: 0.63-0.76]). **CONCLUSIONS:** All these early response markers have high PPV and high specificity but low-to-moderate sensitivity: 80% to 100% of patients identified as "insufficient-responders" by W12 would fail to fulfil the ACR50 response at W52. Such predictability data for certolizumab pegol should help physicians to make early decisions about the potential discontinuation of the treatment.

PMS10

THE 3D O-ARM SURGICAL IMAGING SYSTEM WITH NAVIGATION EFFECTIVELY AND ECONOMICALLY ADDRESSES THE CHALLENGES OF SPINAL STABILIZATION PROCEDURES

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BACKGROUND: Inaccurate pedicle screw placement and neurological or vascular injury during spinal instrumentation procedures is both costly and preventable. **OBJECTIVES:** To determine the comparative efficacy or effectiveness and value for money of the 3D O-arm Surgical Imaging System with Navigation during spinal stabilization surgery compared with standard practice. **METHODS:** A search of Medical and Health Economic electronic databases (Embase, PubMed, HEED, NHS EED, Cochrane) and conference abstracts up to Nov. 2012 was conducted to identify studies evaluating the effectiveness, efficacy and economics of 3D surgical imaging with navigation. No time or language restrictions were applied. **RESULTS:** Compared with current practice options, the 3D O-arm surgical imaging with navigation was shown to significantly increase the accuracy of instrument placement, reduce surgeons' and patients' exposure to radiation, and offer the opportunity for intraoperative revision for malplaced screws during the index procedure. Results of 10 case series and a European registry show rates of pedicle screw placement accuracy (0 mm to ≤2 mm) between 95% and 100% with 3D O-arm surgical imaging with navigation compared to 84% - 95% reported for various current practice options from multiple meta-analyses. In addition, accuracy rates of between 72% and 92% have been reported for 2D C-arm without navigation. Economic studies demonstrated 3D O-arm surgical imaging with navigation has the potential to reduce the cost of fusion procedures in Europe and the USA by negating the need for pre-operative and post-operative imaging associated with current standard-of-care, reducing the need for reoperations for screw revision, shortening length of procedures and OR time. It has been estimated that it could reduce the cost of hospitalization for spinal surgery by at least 3.8%. **CONCLUSIONS:** Current evidence shows 3D O-arm surgical imaging with navigation substantially reduces the human and financial burden of patients during spinal stabilization surgery compared with standard practice.

PMS11

EVALUATING THE EFFICACY OF BIOSIMILAR INFLIXIMAB WITH THE ACR50 RESPONSE IN PATIENTS WITH RHEUMATOID ARTHRITIS; A META-ANALYSIS IN BAYESIAN FRAMEWORK

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OBJECTIVES: To identify all relevant literature on clinical efficacy and safety evidence for biosimilar infliximab (CT-P13) and comparator biological medications in rheumatoid arthritis and to conduct an up-to-date meta-analysis. **METHODS:** The following comparators were considered for this analysis: abatacept, adalimumab, certolizumab, etanercept, golimumab, infliximab, rituximab and tocilizumab. A MEDLINE search was conducted until March 2013. The Cochrane Highly Sensitive Search Strategy was applied to identify randomized controlled publications and was combined with 'arthritis, rheumatoid' MeSH terms and drug names. Randomized, controlled, clinical trials with adults with moderate-to-severe RA and reporting endpoints for 6 months where the full paper can be obtained were included. Direct and indirect evidences were combined in a mixed treatment comparisons in a Bayesian framework. Efficacy measured by ACR50 endpoint and frequency of serious adverse events at 24-30 weeks were analysed. **RESULTS:** Altogether 41 trials were included into current meta-analysis. The relative odds ratios (and 95% credible intervals) for ACR50 of biosimilar infliximab treatments compared to abatacept, adalimumab, certolizumab, etanercept, golimumab, rituximab, tocilizumab and infliximab were 1.0 (0.3-3.8), 0.9 (0.2-3.4), 0.3 (0.1-1.4), 1.0 (0.2-4.2), 1.2 (0.3-5.1), 0.9 (0.2-3.6), 0.5 (0.1-2.2), 1.0 (0.3-3.2), respectively. Similarly, relative odds ratios for serious adverse events were 1.9 (0.8-4.8), 2.0 (0.6-5.8), 0.7 (0.2-2.1), 2.0 (0.8-5.7), 1.5 (0.5-4.2), 1.1 (0.7-2.0), 1.3 (0.8-2.2), 1.3 (0.8-2.1), respectively. **CONCLUSIONS:** The results showed that efficacy and safety of biosimilar infliximab is not significantly different from innovator infliximab and from other biologics.

PMS12

SYSTEMATIC REVIEW COMPARING THE EFFICACY AND SAFETY OF COLLAGENASE CLOSTRIDIUM HISTOLYTICUM (XIAFLEX®) INJECTION WITH SURGICAL FASCIECTOMY FOR THE TREATMENT OF DUPUYTREN'S CONTRACTURE

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OBJECTIVES: To compare the efficacy and safety of collagenase clostridium histolyticum (CCH, Xiaflex®) injection with surgical fasciectomy for the treatment of Dupuytren's contracture (DC). **METHODS:** Systematic review and qualitative synthesis of comparative and non-comparative studies reporting efficacy (clinical success, recurrence of contracture) and safety (complication) outcomes for patients undergoing fasciectomy for DC. Informal non-statistical comparison with outcomes from 3 pivotal placebo controlled trials and a long term follow-up study of DC patients treated with CCH. **RESULTS:** Sixty-eight studies of fasciectomy were identified for inclusion in the review: 61 case series (52 retrospective; 9 prospective); 3 randomised controlled trials (RCTs), none of which permitted either a direct comparison with CCH or an indirect comparison via a common comparator; 1 RCT follow-up study; 2 prospective uncontrolled studies; 1 postal survey. Studies varied in terms of fasciectomy technique employed. Follow-up ranged from only immediately post-operatively up to 35 years post-operatively. Definitions of surgical success and recurrence varied, and were frequently ill-defined or less stringent than the robust definitions used in the CCH trials. In studies of fasciectomy where definitions were judged as reasonably comparable to those used in the CCH trials (clinical success: 14 studies; recurrence: 40 studies), clinical success and recurrence rates for CCH and fasciectomy were comparable (clinical success: 63% vs 69% respectively, recurrence: 28% vs 21% at 4 years, respectively). Complication rates were greater for fasciectomy than for CCH. These included digital nerve or artery injury (3.3% vs 0%), complex regional pain syndrome (3.6% vs 0.04%), joint stiffening (8.9% vs 0%), wound infection (6.2% vs 0%), and paraesthesia (4.3% vs 0%). Tendon ruptures were reported with CCH, but were infrequent (0.07%). **CONCLUSIONS:** CCH and surgical fasciectomy can be reasonably considered as comparable in terms of efficacy for the treatment of DC and superior in terms of safety.

PMS13

COMPARATIVE EFFECTIVENESS OF ACTIVE VERSUS SHAM ACUPUNCTURE VERSUS USUAL CARE IN THE MANAGEMENT OF CHRONIC, NON-CANCER PAIN IN PRIMARY CARE

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OBJECTIVES: To examine the effectiveness of acupuncture net of sham effect and usual care, measured using EQ-5D, in the management of chronic, non-cancer pain in primary care. Systematic reviews of acupuncture for the conditions osteoarthritis